

REMARKS

Claims 1-44 are pending in the above-referenced application. In the Office Action, Claims 1-6, 8, 9, 11-33, 35, 37, 38 and 42-44 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 7,008,431 to Simonson (hereinafter "Simonson") and further in view of U.S. Patent No. 5,006,113 to Fischer (hereinafter "Fischer") and U.S. Patent No. 4,449,532 to Storz (hereinafter "Storz"). Claims 7 and 36 were rejected under 35 U.S.C. §103(a) as being unpatentable over Simonson and further in view of Fischer and Storz as applied to claims 1 and 31 and further in view of U.S. Patent No. 4,862,891 to Smith (hereinafter "Smith"). Claims 10 and 39-41 are withdrawn as being drawn to a non-elected invention.

Applicants appreciate the in-person interview generously granted by the Examiner on September 16, 2009. In the interview, the Examiner clarified the previous office action, stating Simonson can be a 102 rejection for several of the claims, and Fischer and Storz are a 103 rejection for the other claims. The Examiner suggested adding threads at the distal tip of the dilators and/or adding the structure that is seen in the current application in Figure 2, element 156b in order to overcome the previous rejection. The Examiner will update the search upon receiving a response.

Based on the clarification presented in the interview, Applicant assumes that the 102(b) rejection under Simonson applies to claims 1-6, 8-9, and 42-44, and that the 103(a) rejection under Fischer and Storz applies to claims 11-33, 35, 37, and 38. It would therefore follow that claim 7 is now rejected under 35 U.S.C. §103(a) as being unpatentable over Simonson as applied to claim 1 and further in view of Smith, and that claim 36 is now rejected as being unpatentable over Fischer and Storz as applied to claim 31 and further in view of Smith. The discussion below is based upon those assumptions. The Examiner is requested to notify Applicant if those assumptions are in error.

By this paper, independent claims 1, 11, 19, 31 and 42 have been amended as suggested during the interview. Claims 2, 20, 22, 32, 33, 37, 38 and 43 have been amended to reflect amended language in the independent claims from which they respectively depend. Claim 35 has been canceled, and its claimed subject matter has been incorporated into independent claim 31. Claims 3 and 15 have been amended to correct claim dependence. In addition, independent claim 26 has been amended to more clearly set forth what the Applicants regard as their invention. Claim 45 is newly

presented, and does not include any new matter. Support for claim 45 may be found in Figure 2 and paragraph [0040].

For at least the following reasons, claims 1-9, 11-38 and 42-45 are believed to be in a condition for allowance.

REJECTION OF CLAIMS 1-6, 8-9 AND 42-44 UNDER 35 U.S.C. §102 TO SIMONSON

Claims 1-6, 8-9, and 42-44 are rejected under 35 U.S.C. §102(b) as being anticipated by Simonson. Independent claims 1 and 42 have been amended as suggested in the interview, and possesses clear novelty over Simonson.

Claim 1 has been amended to include the limitation of a first mating member formed on the exterior surface of the first dilator at the distal insertion end, so that the second dilator mechanically engages with the first mating member such that the second dilator is forced to travel along a fixed path that prevents free rotation of the second dilator relative to the first dilator while at least a portion of the second dilator is being advanced over the first dilator. Simonson does not disclose any mating members formed on the exterior surface of a first dilator, and therefore none at a distal insertion end. Simonson also does not disclose engagement of a second dilator with such a mating member so as to prevent free rotation of the second dilator relative to the first dilator.

Claim 42 has been amended similarly to claim 1 and includes the limitation of mechanically engaging the first dilator with a mating member formed at the distal insertion end of a second dilator so as to prevent free rotation of the second dilator around the first dilator. As argued with regard to claim 1, Simonson does not disclose a mating member, or mechanically engaging a second dilator with a mating member to prevent free rotation of the second dilator relative to the first dilator.

Since the prior art reference does not anticipate all limitations of independent claims 1 and 42, withdrawal of the rejection is respectfully requested. Claims 2-6, 8 and 9 depend from claim 1 and are not anticipated for the same reasons. Claims 43 and 44 depend from claim 42 and are likewise not anticipated.

REJECTION OF CLAIMS 11-33, 35, 37 AND 38 UNDER 35 U.S.C. §103 OVER FISCHER IN VIEW OF STORZ

Claims 11-33, 35, 37 and 38 stand rejected under 35 U.S.C. §103(a) over Fischer in view of Storz. Independent claims 11, 19, 26, and 31 have been amended as suggested by the Examiner in the interview, and include limitations not found in the prior art combination.

Independent claim 11 includes the limitation of means for forcing the second dilator to travel along a substantially fixed path that prevents free rotation of second dilator relative to the first dilator while at least a portion of the second dilator is being advanced over the first dilator, such means being located at the distal insertion ends of both the first and second dilators. Applicants' specification, paragraph [0062], clearly defines what is meant by the means for limitation for the purposes of the claimed invention. Neither Fischer, nor Storz or the combination thereof discloses such means or any equivalents. Since all claim limitations must be considered and are not found in the combination of prior art references, a *prima facie* case of obviousness has not been established. Claims 12-18 depend from claim 11 and are non-obvious for the same reasons.

Independent claim 19 includes the limitations, *inter alia*, of a first mating member being formed on the exterior surface of the first tubular body at the distal insertion end, and a second mating member comprising a projecting tang formed on the interior surface of the second tubular body. Storz includes no mating members whatsoever, and the threads disclosed by Fischer are not located at a distal insertion end of a tubular body, nor comprise a projecting tang. Since all claim limitations must be considered and are not found in the combination of prior art references, a *prima facie* case of obviousness has not been established. Claims 20-25 depend from claim 19 and are non-obvious for the same reasons.

Independent claim 26 includes the limitation of an elongate first dilator with a first tissue member formed on an outwardly projecting from the exterior surface of the first tubular body at or toward the distal insertion end. Storz discloses no tissue engaging members formed on and/or outwardly projecting from the exterior surface of a tubular body. The distal end 14 of tube 4 is simply the end of a tube and is not formed on, nor does it outwardly project from, the exterior surface (emphasis added) of the tube. Fischer does not disclose any tissue-engaging members, as it is drawn to a hemostatis cannula which does not engage bodily tissues. In addition, Fischer does not disclose

any outwardly projecting member of any kind formed from an exterior surface of a tubular body at or toward a distal insertion end. Since all claim limitations must be considered and are not found in the combination of prior art references, a *prima facie* case of obviousness has not been established. Claims 27-30 depend from claim 26 and are non-obvious for the same reasons.

Independent claim 31 is drawn to a dilator and includes the limitation of a first mating member comprising a projecting tang and formed on the interior surface of a tubular body, and a second mating member formed on the exterior surface of the tubular body. Storz discloses no mating members whatsoever, whether formed on the interior or exterior surface of a tubular body, and certainly not formed on both surfaces. Fischer discloses threads on a cannula, but does not disclose a mating member which is a projecting tang. Fischer also does not disclose a singular tubular body with a mating member formed on an interior surface and a mating member formed on an exterior surface. Since all claim limitations must be considered and are not found in the combination of prior art references, a *prima facie* case of obviousness has not been established. Claims 32-38 depend from claim 31 and are non-obvious for the same reasons.

REJECTION OF CLAIM 7 UNDER 35 U.S.C. §103 OVER SIMONSON IN VIEW OF SMITH

Claim 7 is rejected under 35 U.S.C. §103(a) as being unpatentable over Simonson in view of Smith. The rejection sets forth that Simonson teaches the claimed invention but does not specify the geometry of the dilator. However, as set forth above regarding the 102(b) rejection to claim 1, Simonson does not disclose all the limitations recited in independent claim 1, specifically a first mating member formed on the exterior surface of the first dilator at the distal insertion end, and the second dilator mechanically engaging with the first mating member to prevent free rotation of the second dilator relative to the first dilator. Smith also does not disclose such a mating member or such mechanical engagement to prevent free rotation between the dilators. The combination of Simonson and Smith does not teach or suggest all the limitations of the independent claim from which claim 7 depends; therefore claim 7 is patentable over the cited combination for at least the reasons set forth above. Withdrawal of the rejection is respectfully requested.

REJECTION OF CLAIM 36 UNDER 35 U.S.C. §103 OVER FISCHER AND STORZ IN VIEW OF SMITH

Claim 36 is rejected under 35 U.S.C. §103(a) as being unpatentable over Fischer and Storz in further view of Smith. The rejection sets forth that Storz and Fischer teach the claimed invention but do not specify the geometry of the dilator. However, as set forth above regarding the 103(a) rejection to claim 31, Storz and Fischer do not disclose all the limitations recited in the independent claim. Neither Fischer nor Storz disclose a mating member comprising a projecting tang, nor a dilator with a first mating member formed on an interior surface and a second mating member formed on an exterior surface. Smith also does not disclose a mating member comprising a projecting tang, nor a dilator with a first mating member formed on an interior surface and a second mating member formed on an exterior surface. The combination of Storz, Fischer and Smith does not teach or suggest all the limitations of independent claim 31 from which claim 36 depends; therefore claim 36 is patentable over the cited combination for at least the reasons set forth above. Withdrawal of the rejection is respectfully requested.

CONCLUSION

Claims 1-9, 11-38 and 42-45 are believed to be in condition for allowance. If there are any remaining issues preventing mailing of a Notice of Allowance, the Examiner is respectfully requested to contact the undersigned.

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Respectfully submitted,

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